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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,477	04/20/2004	Swee Hin Teoh	NUS-8 DIV I	4933

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EXAMINER

WOODWARD, CHERIE MICHELLE

ART UNIT	PAPER NUMBER
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1647

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/828,477	Applicant(s) TEOH ET AL.	
	Examiner Cherie M. Woodward	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Formal Matters

1. Claims 40-48 are pending. Claims 1-39 and 49 have been cancelled by Applicant in a Preliminary Amendment. Claims 40-48 are under examination.

Specification

2. The use of the trademarks QUICKSLICE (pp. 16, 33), STRATASYS (pp. 16, 33, 34, 36, 48, 49), SUPPORTWORKS (p. 16), ALDRICH (p. 30), GIBCO (p. 56), HYCLONE (p. 57), MERCK (p. 58), MOLECULAR PROBES (pp. 58-59), OLYMPUS (p. 58), and FLUOVIEW (p. 58) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
4. Claims 40-48 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 40 recites an apparatus for use in tissue engineering, said apparatus comprising: a scaffold structure being formed of a plurality of horizontal layers of material, vertical walls forming each of said plurality of horizontal layers of material, said walls of each layer of said plurality of horizontal layers each having a height, each being horizontally separated from one another, and defining an orientation, adjacent pairs of said vertical walls of each of said plurality of horizontal layers of material forming channels therebetween, said channels having a depth and a width created by said height of said walls and said horizontal separation of said adjacent pairs of said vertical walls, respectively, adjacent layers in said plurality of horizontal layers of material being in different orientation to one another wherein said orientation defined by adjacent ones of said each layer of material being in different orientations to one another wherein said orientation defined by adjacent ones of said each layer of said walls of said plurality of horizontal layers differ from one another, said different orientations providing a group of cross-points to allow adhesion between said adjacent layers and providing interconnectivity

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between said channels throughout said scaffold structure. Claim 40, as written describes naturally occurring compositions of matter, including sponges and cadaver bones, which are products of nature.

Claims 41-48 are rejected as being dependent on a rejected claim.

Claim Rejections - 35 USC § 112, First Paragraph

Written Description

5. Claims 40-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claims recite an apparatus for use in tissue engineering, said apparatus comprising: a scaffold structure being formed of a plurality of horizontal layers of material, vertical walls forming each of said plurality of horizontal layers of material, said walls of each layer of said plurality of horizontal layers each having a height, each being horizontally separated from one another, and defining an orientation, adjacent pairs of said vertical walls of each of said plurality of horizontal layers of material forming channels therebetween, said channels having a depth and a width created by said height of said walls and said horizontal separation of said adjacent pairs of said vertical walls, respectively, adjacent layers in said plurality of horizontal layers of material being in different orientation to one another wherein said orientation defined by adjacent ones of said each layer of material being in different orientations to one another wherein said orientation defined by adjacent ones of said each layer of said walls of said plurality of horizontal layers differ from one another, said different orientations providing a group of cross-points to allow adhesion between said adjacent layers and providing interconnectivity between said channels throughout said scaffold structure; wherein said material forming said scaffold structure is a polycaprolactone filament; wherein said material forming said scaffold is a polycaprolactone/hydroxyapatite composite filament; wherein said vertical walls have a linear shape; wherein said vertical walls have a curved shape; wherein said orientation of said walls is a said plurality of horizontal layers of material with respect to said lay-down pattern for a first horizontal layer; wherein said orientation of said walls is a lay-down pattern of 0 [degrees]/90 [degrees]; wherein said orientation of

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said walls is a lay-down pattern of 0 [degrees]/60 [degrees]/120 [degrees]; wherein said orientation of said walls is a lay-down pattern of 0 [degrees]/72 [degrees]/144 [degrees]/36 [degrees]/108 [degrees].

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of the claim indicates that these claims are drawn to a genus, i.e., a three dimensional apparatus for use in tissue engineering having interconnectivity between channels throughout the scaffold structure.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states, "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, i.e. a scaffold fabricated using PCL and PCL/HA filaments with a FDM 3D MODELER rapid prototyping system from STRATASYS, INC (see Example 1, p. 48 of the disclosure). The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described.

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In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which is a three dimensional apparatus for use in tissue engineering having interconnectivity between channels throughout the scaffold structure. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus. The specification does not clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112, Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 40, 46-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite an apparatus for use in tissue engineering having the recited orientation of wall lay-down patterns with particular degree orientations. However, the claims and the disclosure state that the apparatus is to be three-dimensional (i.e. having X, Y, and Z axes). As such it is unclear from the claims or the disclosure where the degree measurements are to begin and end. For example, on one horizontal plane, two intersecting linear components may have multiple degree measurements. If, for example, these intersecting components intersect at a right angle, measurements of 0 degrees, 180 degrees, and 90 degrees may be made in this two dimensional exemplary model. Because the claims are drawn to a lay-down pattern in a three dimensional orientation, it is unclear where the recited degree measurements are to be taken. It is also unclear what the "/" (forward-slash) between the recited degrees is intended to mean. For example, it is unclear whether the forward-slash is meant be read as a 90 degree angle (from 0 to 90 degrees) or whether it means a lay-down orientation at any degree from 0 degrees to 90 degrees.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 40-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Cima et al., US Patent 5,518,680 (21 May 1996, benefit to 23 February 1994).

The claims recite an apparatus for use in tissue engineering, said apparatus comprising: a scaffold structure being formed of a plurality of horizontal layers of material, vertical walls forming each of said plurality of horizontal layers of material, said walls of each layer of said plurality of horizontal layers each having a height, each being horizontally separated from one another, and defining an orientation, adjacent pairs of said vertical walls of each of said plurality of horizontal layers of material forming channels therebetween, said channels having a depth and a width created by said height of said walls and said horizontal separation of said adjacent pairs of said vertical walls, respectively, adjacent layers in said plurality of horizontal layers of material being in different orientation to one another wherein said orientation defined by adjacent ones of said each layer of material being in different orientations to one another wherein said orientation defined by adjacent ones of said each layer of said walls of said plurality of horizontal layers differ from one another, said different orientations providing a group of cross-points to allow adhesion between said adjacent layers and providing interconnectivity between said channels throughout said scaffold structure; wherein said material forming said scaffold structure is a polycaprolactone filament; wherein said material forming said scaffold is a polycaprolactone/hydroxyapatite composite filament; wherein said vertical walls have a linear shape; wherein said vertical walls have a curved shape; wherein said orientation of said walls is a said plurality of horizontal layers of material with respect to said lay-down pattern for a first horizontal layer.

Cima et al., teach a customized scaffold structure for use in tissue engineering for an individual patient as claimed, including the use of scanning and fused deposition modeling (FDM) (abstract; column 1, lines 16-28; and column 2, lines 11-13). Polymers to be used include polycaprolactone (column 8, line

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37) and composites including hydroxyapatite and hydroxyapatite (column 1, line 52 and 63). Incorporate of hydroxyapatite crystals into a matrix for bone regeneration are taught at column 9, lines 64-65.

Example 1 (column 14, lines 3067 to column 15, lines 1-5) teach a bone regeneration matrix comprising three-dimensional multiple layers that comprise complex architectural features and macroscopic shapes, including linear and curved shapes, which can be manipulated by varying the printing instructions.

10. Claims 40, and 43-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Richter et al., US Patent 6,280,478 (28 August 2001), benefit to 4 January 1999).

The claims recite an apparatus for use in tissue engineering, said apparatus comprising: a scaffold structure being formed of a plurality of horizontal layers of material, vertical walls forming each of said plurality of horizontal layers of material, said walls of each layer of said plurality of horizontal layers each having a height, each being horizontally separated from one another, and defining an orientation, adjacent pairs of said vertical walls of each of said plurality of horizontal layers of material forming channels therebetween, said channels having a depth and a width created by said height of said walls and said horizontal separation of said adjacent pairs of said vertical walls, respectively, adjacent layers in said plurality of horizontal layers of material being in different orientation to one another wherein said orientation defined by adjacent ones of said each layer of material being in different orientations to one another wherein said orientation defined by adjacent ones of said each layer of said walls of said plurality of horizontal layers differ from one another, said different orientations providing a group of cross-points to allow adhesion between said adjacent layers and providing interconnectivity between said channels throughout said scaffold structure; wherein said material forming said scaffold structure is a polycaprolactone filament; wherein said material forming said scaffold is a polycaprolactone/hydroxyapatite composite filament; wherein said vertical walls have a linear shape; wherein said vertical walls have a curved shape; wherein said orientation of said walls is a said plurality of horizontal layers of material with respect to said lay-down pattern for a first horizontal layer; wherein said orientation of said walls is a lay-down pattern of 0 [degrees]/90 [degrees].

Richter et al., teaches a customized three-dimensional, layered, scaffold structure for use in tissue engineering for an individual patient including the aspect of intercrossing filaments stacked in horizontal planes (see abstract; Figures 1 and 2; Examples 1 and 2, columns 3 and 4). Interconnected pores or channels are taught at column 1, line 27. Linear components and curved components are taught in Figure 1 and column 3, lines 1-34, especially lines 33-34. Components that can extend at any angle between 10

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degrees and 90 degrees relative to those of an adjacent component are taught at column 3, lines 21-23 (see also column 4, lines 50-54).

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CMW

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JANET L. ANDRES
SUPERVISORY PATENT EXAMINER